William L. Mentlik
Arnold I. Rady
April M. Capati
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, NJ 07090-1497
Tel: 908.654.5000
Fax: 908.654.7866

Attorneys for Plaintiff Paddock Laboratories, Inc.

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PADDOCK LABORATORIES, INC., Plaintiff, v. ETHYPHARM S.A., LUPIN LIMITED, and LUPIN PHARMACEUTICALS, INC., Defendants.	:	Civil Action No. 09-3779-GEB-LHG

AMENDED COMPLAINT

Plaintiff Paddock Laboratories, Inc. ("Paddock"), by its undersigned attorneys, for its amended complaint against defendant Ethypharm S.A. ("Ethypharm"), a corporation organized and existing under the laws of the Republic of France with a United States affiliate Ethypharm Corporation, a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at 821 Alexander Road, Princeton, New Jersey 08540, and defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (individually and jointly "Lupin") (Ethypharm and Lupin collectively "Defendants") herein, alleges as follows:

NATURE OF THE ACTION

1. This is an action seeking a declaratory judgment of noninfringement and invalidity of United States Patent No. 7,101,574 ("the '574 Patent") pursuant to the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*; the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(5)(C)(i); and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202; 21 U.S.C. § 55(j)(5)(C)(i)(II); and 35 U.S.C. § 271(e)(5).

3. This Court has personal jurisdiction over Ethypharm based on, *inter alia*, its significant business activities in this judicial district, such as soliciting business in and deriving substantial revenue from this judicial district, including through its United States affiliate Ethypharm Corporation, a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at 821 Alexander Road, Princeton, New Jersey 08540.

4. This Court has personal jurisdiction over Lupin Limited based on, *inter alia*, its significant business activities in this judicial district, such as soliciting business in and deriving substantial revenue from this judicial district, including through its wholly owned United States subsidiary Lupin Pharmaceuticals, Inc.

5. This Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. based on, *inter alia*, its significant business activities in this judicial district, such as soliciting business in and deriving substantial revenue from this judicial district.

6. This Court has personal jurisdiction over Defendants based on exclusive field-of-use licensing agreement(s) of the '574 Patent that impose obligations to enforce the

'574 Patent, and/or other activities that relate to the enforcement or defense of the '574 Patent, with parties residing or regularly doing business in this judicial district.

7. Accordingly, this Court may assert personal jurisdiction and personal jurisdiction exists over Defendants.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b), and 21 U.S.C. § 55(j)(5)(C)(i)(II) in that, *inter alia*, a substantial part of the events or omissions giving rise to the claims asserted occurred in this judicial district, including exclusive field-of-use licensing of the '574 Patent with certain obligations to enforce the '574 Patent, and/or other activities that relate to the enforcement or defense of the '574 Patent, with parties residing or regularly doing business in this judicial district.

THE PARTIES

9. Plaintiff Paddock is a corporation organized and existing under the laws of the State of Minnesota, with its headquarters and principal place of business at 3940 Quebec Avenue North, Minneapolis, Minnesota 55427.

10. Upon information and belief, defendant Ethypharm is a corporation organized and existing under the laws of the Republic of France, with a principal place of business at 194 Bureaux de la Colline, 922 13 Saint Cloud, France.

11. Upon information and belief, defendant Lupin Limited is a corporation organized and existing under the laws of India, with a principal place of business at B/4 Laxmi Towers, Bandra Kuria Complex, Bandra (W), Mumbai 400 051, India.

12. Upon information and belief, defendant Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Lupin Limited and is a corporation organized and existing under the laws of Commonwealth of Virginia, with a principal place of business at Harborplace Tower, 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202.

FACTUAL BACKGROUND

13. The '574 Patent, entitled "Pharmaceutical Composition Containing Fenofibrate and the Preparation Method," issued on September 5, 2006, to Laboratoires des Produits Ethiques Ethypharm. Upon information and belief, Ethypharm is currently the owner of the '574 Patent.

14. Upon information and belief, on or about May 7, 2001, Ethypharm granted an exclusive field-of-use license to Reliant Pharmaceuticals LLC ("Reliant"), a corporation with a principal place of business at 110 Allen Road, Liberty Corner, New Jersey 07938 ("the Ethypharm-Reliant license").

15. Upon information and belief, the Ethypharm-Reliant license agreement imposes obligations to enforce the '574 Patent.

16. Upon information and belief, the Ethypharm-Reliant license is governed by the laws of the State of New Jersey.

17. Upon information and belief, pursuant to the Ethypharm-Reliant license, Reliant sought and obtained United States Food and Drug Administration ("FDA") approval for, and marketed, sold, and distributed ANTARA® (micronized fenofibrate) capsules, 43 mg and 130 mg ("the ANTARA® Product").

18. Upon information and belief, FDA approved ANTARA® under New Drug Application ("NDA") No. 21-695 on November 30, 2004 ("the ANTARA® NDA").

19. Upon information and belief, Ethypharm is the party directly responsible for the development, manufacture, and entry of the ANTARA® Product into the fenofibrate market throughout the United States, including the State of New Jersey.

20. Upon information and belief, on or about August 2006, Reliant sold its rights under the '574 Patent and to the ANTARA® Product to Oscient Pharmaceuticals Corporation

("Oscient"), a corporation registered to do business in the State of New Jersey, and with commercial sales and marketing operations at 23 Orchard Road, Skillman, New Jersey 08558 ("the Ethypharm-Oscient license").

21. Upon information and belief, Oscient assumed Reliant's duties and obligations under the Ethypharm-Reliant license, including but not limited to the obligation to launch and promote, and otherwise commercialize, the ANTARA® Product throughout the United States, including the State of New Jersey.

22. Upon information and belief, the Ethypharm-Oscient license agreement imposes obligations to enforce the '574 Patent.

23. Upon information and belief, the Ethypharm-Oscient license is governed by the laws of the State of New Jersey.

24. Upon information and belief, Ethypharm, by virtue of the Ethypharm-Reliant license, caused FDA to list the '574 Patent in FDA's publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the *Orange Book")* in connection with ANTARA® as a patent that could reasonably be asserted against anyone marketing or seeking to market unlicensed fenofibrate capsules.

25. Upon information and belief, Defendants continue to maintain the listing of the '574 Patent in the *Orange Book* in connection with ANTARA®.

26. By listing and maintaining the listing of the '574 Patent in the *Orange Book* in connection with ANTARA®, Defendants created and maintain a legal uncertainty that they would file a patent infringement action against Abbreviated New Drug Application ("ANDA") applicants seeking FDA approval to market generic fenofibrate capsules.

27. Upon information and belief, defendant Ethypharm has demonstrated an intent to prevent generic competition for ANTARA® by filing a lawsuit asserting the '574 Patent against another ANDA applicant, defendant Lupin, which had previously sought FDA approval to market generic fenofibrate capsules based on the ANTARA® NDA. *Oscient Pharms. Corp., Guardian II Acquisition Corp. and Ethypharm S.A. v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.,* No. 090083 (D. Md. filed Jan. 14, 2009) ("the Lupin Action"). In the Answer to the Complaint filed by defendant Lupin in the Lupin action, Lupin asserted that the claims of the '574 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101 *et seq.*

28. Upon information and belief, defendant Lupin was the first generic applicant to file an ANDA seeking FDA approval to market generic fenofibrate capsules based on the ANTARA® NDA ("Lupin's ANDA"). Upon information and belief, as part of defendant Lupin's ANDA, Lupin included a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R § 314.94(a)(12)(i)(A)(4) that the '574 Patent will not be infringed and/or the '574 Patent is invalid ("Lupin's Paragraph IV Certification").

29. Upon information and belief, the Lupin action was brought within the statutory 45-day period, staying FDA from granting final approval to Lupin's ANDA for 30 months subject to certain conditions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

30. Upon information and belief, on or about July 2009, Oscient and its wholly owned subsidiary, Guardian II Acquisition Corporation, each filed a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts.

31. Upon information and belief, on or about September 2009, defendant Lupin successfully bid to acquire Oscient's rights under the '574 Patent, the ANTARA® NDA, and to the ANTARA® Product under the procedures of the United States Bankruptcy Court.

32. Upon information and belief, on or about September 2009, defendant Lupin acquired Oscient's rights under the '574 Patent, the ANTARA® NDA, and to the ANTARA® Product under the procedures of the United States Bankruptcy Court.

33. Upon information and belief, on or about September 2009, Dr. Reddy's Laboratories Ltd. ("DRL") acquired the rights to defendant Lupin's ANDA, including the right to market generic fenofibrate capsules under Lupin's ANDA some time prior to August 20, 2020, the expiration date of the '574 Patent.

34. Upon information and belief, on or about October 2009, the Lupin action was settled.

35. As a result, DRL may be entitled to a generic marketing exclusivity period during which FDA may not approve other generic fenofibrate capsule ANDAs based on the ANTARA® NDA. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

36. Upon information and belief, the '574 Patent continues to be listed in the *Orange Book* in connection with ANTARA®.

37. By maintaining the listing of the '574 Patent in the *Orange Book* in connection with ANTARA®, defendants Ethypharm and Lupin maintain a legal uncertainty that they would file a patent infringement action against ANDA applicants seeking FDA approval to market generic fenofibrate capsules.

38. Paddock filed ANDA No. 91-362 ("Paddock's ANDA") seeking FDA approval to market generic fenofibrate capsules, 43 mg and 130 mg, based on the ANTARA® NDA

("Paddock's Proposed Product"). As part of Paddock's ANDA, Paddock included a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R § 314.94(a)(12)(i)(A)(4) that the '574 Patent will not be infringed by Paddock's Proposed Product, and/or the '574 Patent is invalid, and seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Paddock's Proposed Product prior to the expiration of the '574 Patent ("Paddock's Paragraph IV Certification").

39. Paddock provided notice of its Paragraph IV Certification by letter addressed to Ethypharm and Oscient dated May 15, 2009, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ("Paddock's Notice Letter"). Paddock's Notice Letter was accompanied by an offer of confidential access to Paddock's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) for the purpose of determining whether an infringement action should be brought.

40. Upon information and belief, Ethypharm and Oscient received Paddock's Notice Letter on or about May 26, 2009.

41. Paddock's Notice Letter initiated a 45-day statutory period during which Ethypharm and/or Oscient had the opportunity to file an action for patent infringement.

42. Before the 45-day statutory period expired, Paddock provided a confidential copy of Paddock's ANDA to counsel for Ethypharm and Oscient.

43. Ethypharm and Oscient did not bring an action for patent infringement before the 45-day period expired.

44. Defendants have not yet brought an action for patent infringement against Paddock.

CLAIM FOR RELIEF

Declaratory Judgment Of Noninfringement And Invalidity Of The '574 Patent

45. Paddock reasserts and realleges each of the foregoing paragraphs as if fully set forth herein.

46. Since no action for patent infringement was filed within the 45-day statutory period, a civil action may be brought by Paddock, as a generic applicant, to obtain patent certainty pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(II) and 35 U.S.C. § 271(e)(5), and 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and allow Paddock to obtain a declaratory judgment with respect to the '574 Patent.

47. Notwithstanding the fact that Defendants have not yet brought an action for patent infringement, Defendants are not precluded from individually and/or collectively bringing an action for patent infringement at a later time.

48. Defendants' conduct has created an uncertainty of legal rights with respect to the '574 Patent and Paddock's ANDA.

49. Defendants have caused an injury-in-fact by settling the Lupin Action, thereby restraining Paddock from commercially marketing Paddock's noninfringing generic fenofibrate capsule products.

50. For example, the settlement of the Lupin Action left undecided the validity of the '574 Patent, which was an issue in the Lupin Action in view of the assertion of invalidity of the '574 Patent in Lupin's Answer and Counterclaim filed in the Lupin Action.

51. Paddock seeks FDA approval to market Paddock's Proposed Products. By preparing and filing its ANDA, Paddock has made, and will continue to make, substantial preparations to make, use, sell, offer to sell, and/or import its Proposed Product in the United States before the expiration of the '574 Patent.

52. A case or controversy thus exists between Paddock and Defendants concerning the issues of validity and infringement of the '574 Patent, which requires a declaration of rights by this Court.

53. The '574 Patent generally concerns a fenofibrate composition in the form of granules wherein each granule comprises a neutral microgranule on which is a composition of fenofibrate, a surfactant, and a binding cellulose derivative, in various amounts and relationships including, *inter alia:* (i) greater than or equal to 60% fenofibrate; (ii) between 2 to 15% binding cellulose derivative; and (iii) a mass ratio between 5/1 and 15/1 of fenofibrate to binding cellulose derivative.

54. Paddock does not infringe any claim of the '574 Patent, literally or under the doctrine of equivalents, for at least the following reasons: Paddock's Proposed Product (i) contains no neutral microgranules; (ii) lacks more than 60% fenofibrate by weight; (iii) does not contain between 2 to 15% of a binding cellulose derivative; and (iv) does not contain a mass ratio of fenofibrate to binding cellulose derivative of between 5/1 and 15/1.

55. A definite and concrete, real and substantial, justiciable controversy exists that affects the legal relations of Paddock and Defendants herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

56. Paddock is entitled to obtain patent certainty with respect to its ANDA and the '574 Patent in view of the totality of the circumstances, including but not limited to Defendants' conduct and as alleged herein.

57. Paddock's injury-in-fact is redressible by a declaratory judgment that Paddock's Proposed Product does not or will not infringe any claim of the '574 Patent that is both valid and enforceable.

58. Paddock's Paragraph IV Certification included Paddock's statement that the '574 Patent is invalid.

59. The '574 Patent is invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103, and 112.

60. A declaration of rights between the parties is both appropriate and necessary to establish that Paddock's Proposed Product does not infringe any valid claim of the '574 Patent, and allow FDA approval of Paddock's ANDA, which Defendants' actions would otherwise deny Paddock. *See* 21 U.S.C. § 355(j)(5)(D)(i)(1).

61. Paddock is entitled to a declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of Paddock's generic fenofibrate capsules, 43 mg and 130 mg, does not or will not, if marketed, infringe any claim of the '574 Patent either literally or under the doctrine of equivalents.

62. Paddock is entitled to a declaratory judgment that all of the claims of the '574 Patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in its favor and against Defendants and grant the following relief:

A. a judgment declaring that the making, using, selling, offering for sale, and/or importation of Paddock's generic fenofibrate capsules, 43 mg and 130 mg, do not and will not infringe any claim in the '574 Patent;

B. a judgment that all claims of the '574 Patent are invalid.

C. an award to Plaintiff of its costs, reasonable attorney fees, and expenses pursuant to 35 U.S.C. § 285; and

D. an award to Plaintiff of all further and additional relief as the Court deems just and proper.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38(b), plaintiff hereby demands a trial by a jury on all issues so triable.

Respectfully submitted,

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
Attorneys for Plaintiff Paddock Laboratories, Inc.

Dated: January 26, 2010

By: s/ William L. Mentlik
William L. Mentlik
Tel: 908-654-5000
E-mail:wmentlik@ldlkm.com
litigation@ldlkm.com